





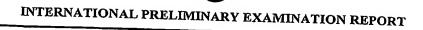
PCT

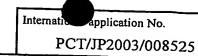
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 09565	FOR FURTHER ACTION		ation of Transmittal of International examination Report (Form PCT/IPEA/416)		
International application No.	International filing date (day/n		Priority date (day/month/year)		
PCT/JP2003/008525	04 July 2003 (04.07.	.2003)	04 July 2002 (04.07.2002)		
International Patent Classification (IPC) or n G01N 33/68, 33/50, 30/88	ational classification and IPC				
Applicant MI	TSUBISHI PHARMA CC	RPORATIO	NO		
and is transmitted to the applicant a	ccording to Article 36.		ational Preliminary Examining Authority		
2. This REPORT consists of a total of	sheets, including	ng this cover st	neet.		
amended and are the basis for	nied by AŃNEXES, i.e., sheets on or this report and/or sheets conta e Administrative Instructions und	ining rectificat	on, claims and/or drawings which have been tions made before this Authority (see Rule		
These annexes consist of a to	otal of sheets.				
3. This report contains indications rela	ating to the following items:				
I Basis of the report					
II Priority	II Priority				
III Non-establishment	of opinion with regard to novel	ty, inventive ste	ep and industrial applicability		
IV Lack of unity of in	vention				
Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement			ventive step or industrial applicability;		
VI Certain documents	cited				
VII Certain defects in t	the international application				
VIII Certain observations on the international application					
Date of submission of the demand	Date	of completion of	of this report		
18 December 2003 (18.	.12.2003)	20	April 2004 (20.04.2004)		
Name and mailing address of the IPEA/JP	Autho	orized officer			
Facsimile No.	Teler	ohone No.			

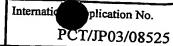
Form PCT/IPEA/409 (cover sheet) (July 1998)





With regard to the elements of the international application:* the international application as originally filed the description: pages	l r. nas	is of the report	
the international application as originally filed the description: pages	1. Wi	th regard to the elements of the internat	innel andications
the description: pages p		the international application as origin	nolly Stad
pages			nany med
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the claims: pages		nages	, as originally filed
the claims: pages pages , as a mended (together with any statement under Article 19 pages , filed with the letter of the drawings: pages pages , as originally filed pages , filed with the letter of the drawings: pages pages , as originally filed pages , filed with the letter of the sequence listing part of the description: pages pages , as originally filed pages , filed with the letter of the drawings, shearting which is: the language of publication was filed, unless otherwise indicated under fulis item. The statement that the subsequently furnished for the purposes of international application, the international application in computer readable form. Item furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The amendments have resulted in the cancellation of: the description, pages the drawings, sheets/file This proport as been c		nages	, filed with the demand
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the drawings: pages page		pages	, as amended (together with any statement under Article 10
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the drawings: pages page		pages	, filed with the letter of
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the sequence listing part of the description: pages pages , filed with the letter of , filed with the letter of , filed with the letter of , filed with the demand pages pages , filed with the letter of With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language which is: the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/ or 55.3). With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing: contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished. The amendments have resulted in the cancellation of: the description, pages the claims, Nos. the drawings, sheets/fig This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "original		pages	, as originally filed
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rang represented street containing such amendments must be referred to under item 1 and annexed to this report.	ana ro.	* · //·	The since they do not contain amenaments (Rule 70.16
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT



III. Non	actablishment of!:	1 C1/JP03/08525
III. INON	establishment of opinion with regard to novelty, inventive step and industrial	applicability
l. The indus	questions whether the claimed invention appears to be novel, to involve an invalve applicable have not been examined in respect of:	ventive step (to be non obvious), or to b
	the entire international application.	
\boxtimes	claims Nos	
becau	se:	
\boxtimes	the said international application, or the said claims Nos. relate to the following subject matter which does not require an international prel The invention of the said claims Nos.	26-28
do Ez	The inventions of claims 26-28 concern a method for diagnoses not require an international preliminary examination by the camining Authority.	
	the description, claims or drawings <i>(indicate particular elements below)</i> or said cla are so unclear that no meaningful opinion could be formed <i>(specify)</i> :	nims Nos.
th by	e claims, or said claims Nos. y the description that no meaningful opinion could be formed.	are so inadequately supported
<u></u>	international search report has been established for said claims Nos.	26-28
A meaning	gful international preliminary examination cannot be carried out due to the failure is the failure to comply with the standard provided for in Annex C of the Administrative	re of the nucleotide and/a
the	isting to comply with the standard provided for in Annex C of the Administrative is written form has not been furnished or does not comply with the standard.	Instructions:
the	e computer readable form has not been furnished or does not comply with the stand	ard.
n PCT/IP	BA/409 (Box III) (July 1998)	





V.	Reasoned statement under Article 35(2) with regard to novelty	, inventive step o	r industrial ap	plicability;
	citations and explanations supporting such statement			

Statement			
Novelty (N)	Claims	1-22, 25	YES
	Claims	23, 24	МО
Inventive step (IS)	Claims	1-22	YES
	Claims	23-25	NO
Industrial applicability (IA)	Claims	1-25	YES
	Claims		

2. Citations and explanations

Document 1: Neuropsychobiology Vol. 31 (1995) p. 10-15

Document 2: JP 61-80051 A (Toyo Soda Manufacturing Co., Ltd.) April 23, 1986

The abstract of document 1 describes the use of plasma serine concentration as a marker for integration dysfunction syndrome. In addition, the Methods section on page 11 describes forming its derivative and measuring that.

Document 2 describes 7-fluoro-4-nitrobenzo-2-oxa-1,3-diazole (NBD-F) as a fluorescent reagent for labeling amino acids.

Claims 23 and 24

Based on the descriptions in documents 1 and 2 cited in the international search report, the inventions of claims 23 and 24 lack novelty. Document 1 discloses the measurement of a labeled amino acid as a marker of integration dysfunction syndrome.

Claim 25

Based on the descriptions in documents 1 and 2 cited in the international search report, the invention of claim 25 lacks an inventive step. Persons skilled in the art can easily conceive of using the NBD-F described in document 2 as a labeling reagent when performing the amino acid measurement described in document 1.

Claims 1-22

None of the documents cited in the international search report or documents that are newly cited in the international preliminary examination report describes a method for detecting integration dysfunction in which the concentration of L-serine or the concentrations of both D-serine and L-serine are measured, and this matter is not obvious to persons skilled in the art.

特許協力条約

PCT

国際予備審査報告

(法第12条、法施行規則第56条) 【PCT36条及びPCT規則70】

REC'D	1 3 MAY 2004
WIPO	PCT

出願人又は代理人 の 智類記号 09565	今後の手続きについては、国際予備審査報告の送付通知(様式PCT/ IPEA/416)を参照すること。					
国際出願番号 PCT/JP03/085.25	国際出顧日 (日.月.年) 04.07.2003 (日.月.年) 04.07.2002					
国際特許分類(IPC) Int.Cl ⁷ G01N3						
出願人(氏名又は名称)	三菱ウェルファーマ株式会社					
1. 国際予備審査機関が作成したこの	国際予備審査報告を法施行規則第57条(PCT36条)の規定に従い送付する。					
2. この国際予備審査報告は、この表紙	紙を含めて全部で4 ページからなる。					
査機関に対してした訂正を含む	この国際予備審査報告には、附属書類、つまり補正されて、この報告の基礎とされた及び/又はこの国際予備審査機関に対してした訂正を含む明細書、請求の範囲及び/又は図面も添付されている。 (PCT規則70.16及びPCT実施細則第607号参照)					
3. この国際予備審査報告は、次の内容	この国際予備審査報告は、次の内容を含む。					
I × 国際予備審査報告の基礎	<u>*</u>					
Ⅱ □ 優先権						
Ⅲ 区 新規性、進歩性又は産業	後上の利用可能性についての国際予備審査報告の不作成 ,					
IV 開の単一性の欠如						
V × PCT35条(2)に規定 の文献及び説明	する新規性、進歩性又は産業上の利用可能性についての見解、それを裏付けるため					
VI ある種の引用文献						
VII 国際出願の不備						
VII 国際出願に対する意見						
	· .					

国際予備審査の請求むを受理した日 18.12.2003	国際予備審査報告を作成した日 20.04.2004
名称及びあて先	特許庁審査官(権限のある職員) 2 J 9 2 1 7
日本国特許庁(IPEA/JP) 郵便番号100-8915	山村 祥子
東京都千代田区霞が関三丁目4番3号	電話番号 03-3581-1101 内線 3251

国際予備審查報告

国際出願番号 . PCT/JP03/08525

						
I.	Ē	国際予備審査報	報告の基礎 			
1.	1. この国際予備審査報告は下記の出願審類に基づいて作成された。 (法第6条 (PCT14条) の規定に基づく命令に 応答するために提出された差し替え用紙は、この報告書において「出願時」とし、本報告書には添付しない。 PCT規則70.16,70.17)					
	×	出願時の国際	条出願咎類			
		明細審 明細審	第 	ページ、 ページ、	出願時に提出されたもの 国際予備審査の請求費と	
		明細書	第	ページ、		付の書簡と共に提出されたもの
	\sqcup		第	項、	出願時に提出されたもの	
		請求の範囲	第	項、	PCT19条の規定に基	
1		請求の範囲	第	項、	国際予備審査の請求審と	
		請求の範囲	第	項、		付の沓簡と共に提出されたもの
		図面	第		出願時に提出されたもの	
		図面	第	ページ/図、	国際予備審査の請求書と	共に提出されたもの
		図面	第	ページ/図、		付の書簡と共に提出されたもの
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l	ш		列表の部分 第	~	国際予備審査の請求書と	
			列表の部分 第	~~;`\		付の書簡と共に提出されたもの
2.	-	上記の出願書類	頭の官語は、下記に示す場	合を除くほか、こ	の国際出願の言語である。	
	_	上記の魯類は、	下記の言語である	語であ	る。	
	1	国際調査	のために提出されたPCT	Γ規則23.1(b)にい	う翻訳文の官語	
	İ	☐ PCT規	!則48.3(b)にいう国際公開	の言語		
		国際予備	i審査のために提出された P	PCT規則55.2また	には55.3にいう翻訳文の 首語	5
3.	,	この国際出願に	は、ヌクレオチド又はアミ	ノ酸配列を含んで	おり、次の配列表に基づき	国際予備審査報告を行った。
	. この国際出願に含まれる魯面による配列表					
	□ この国際出願と共に提出された磁気ディスクによる配列表					
	İ	」 出願後に	、この国際予備審査(また	とは調査)機関に抵	是出された魯面による配列表	₹
] 出願後に	、この国際予備審査(また	とは調査)機関に抵	是出された磁気ディスクに」	る配列表
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		書面によがあった		と磁気ディスクによ	こる配列表に記録した配列か	は同一である旨の陳述書の提出
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4.	$\overline{}$		下記の書類が削除された。			
	빌	明細書	第	ページ		
	Ш	請求の範囲	第	項		
		図面	図面の第	~	ジ/図	
5.		れるので、そ	備審査報告は、補充 构に示 その補正がされなかったも ける判断の際に考慮しなけ	のとして作成した	。(PCT規則70.2(c) こ	囲を越えてされたものと認めら の補正を含む差し替え用紙は上
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国際出願番号 PCT/JP03/08525

Ⅲ. 新規性、進歩性又は産業上の利用可能性についての国際予備審査報告の不作成
1. 次に関して、当該請求の範囲に記載されている発明の新規性、進歩性又は産業上の利用可能性につき、次の理由により 審査しない。
国際出願全体
理由:
▼ この国際出願又は請求の範囲 26-28 は、国際予備審査をすることを要しない
での事項を内容としている(具体的に記載すること)。 請求の範囲26-28は診断方法であり、この国際予備審査機関が国際予備審査をすることを要しない対象に係るものである。
明細書、請求の範囲若しくは図面(次に示す部分)又は請求の範囲
記載が、不明確であるため、見解を示すことができない(具体的に記載すること)。
全部の請求の範囲又は請求の範囲 ************************************
裏付けを欠くため、見解を示すことができない。
▼ 請求の範囲 26-28 について、国際調査報告が作成されていない。
2. ヌクレオチド又はアミノ酸の配列表が実施細則の附属魯C(塩基配列又はアミノ酸配列を含む明細魯等の作成のための ガイドライン)に定める基準を満たしていないので、有効な国際予備審査をすることができない。
□ 書面による配列表が提出されていない又は所定の基準を満たしていない。
│ │ 磁気ディスクによる配列表が提出されていない又は所定の基準を満たしていない。



国際出願番号 PCT/JP03/08525

V.	新規性、進歩性又は産業上の利用可能 文献及び説明	き性についての法第12条 ・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・	(PCT35条(2)) に定める見 	解、それを 嬰付ける
1.	見解			
	新規性(N)	請求の範囲 請求の範囲	1-22, 25 23, 24	
	進歩性(IS) ·	請求の範囲 請求の範囲	1 <u>- 2 2</u> 2 3 - 2 5	
	産業上の利用可能性(IA)	請求の範囲 請求の範囲	1 - 2 5	

文献及び説明 (PCT規則70.7)

文献 1: Neuropsychobiology Vol. 31 (1995) p. 10-15

文献 2: JP 61-80051 A (東洋曹達工業株式会社) 1986.04.23

文献1、abstractには、血漿中のセリン濃度を統合失調症のマーカーとして使用す ることが記載されている。また、第11頁methodsには誘導体化して測定することが 記載されている。

文献2には、アミノ酸蛍光標識試薬として7-フルオロー4-ニトロベンゾー2-オキサー1,3-ジアゾール(NBD-F)が記載されている。

請求項23,24について

請求の範囲23及び24に記載された発明は、国際調査報告で引用された文献1及 び2から新規性を有さない。文献1には、統合失調症のマーカーとして標識化された アミノ酸を測定することが示されている。

請求項25について

請求の範囲25に記載された発明は、国際調査報告で引用された文献1、2より進 歩性を有しない。文献1のアミノ酸測定の際に文献2に記載されたNBD-Fを標識 試薬として採用することは当業者であれば容易に想到し得たものである。

請求項1-22について

生体試料中のD型セリン、L型セリン又はD型セリン及びL型セリンの濃度を測定する統合失調症の検査方法は、国際調査報告で列記した文献、及び国際予備審査報告にて新たに引用した文献のいずれにも記載されておらず、当業者にとって自明なもの でもない。